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WRITER'S INTERNET ADDRESS:
MBELLINGER@FULBRIGHT.COM

WRITER'S DIRECT DIAL NUMBER:
512/536-2487

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March 30, 2001

FILE: UTSC:648

10019711

CERTIFICATE OF EXPRESS MAILING	
NUMBER	EL548525828US
DATE OF DEPOSIT	March 30, 2001

Box DAC
Commissioner for Patents
Washington, DC 20231

RE: SN 09/721,040 "LIPOSOMAL IMEXON" – Lopez-Berestein et al. (UTMDACC:648)

Commissioner:

Enclosed for filing in the above-referenced patent application is:

- (1) A Petition to Convert Nonprovisional Application to Provisional Application (37 C.F.R. §1.53(C)(2);
- (2) A check for \$50.00 as the fee for the Petition; and
- (3) A return postcard to acknowledge receipt of these materials. Please date stamp and mail this postcard.

If the check is inadvertently omitted, or the amount is insufficient, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski L.L.P. Account No.: 50-1212/10019711/MSB10145.

Respectfully submitted,

Matt Bellinger

Matt Bellinger
Reg. No. 46,547

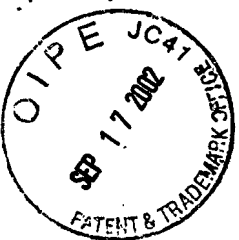
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March 30, 2001

Page 2

bcc: BethLynn Maxwell, Ph.D. (w/o encl.)
Ms. Cheryl M. McCants (w/encl.) for distribution to:
Kevin Casement, Ph.D.
Gabriel Lopez-Bernstein, M.D. (w/ encl.)
Dr. William A. Reemers (w/ encl.)
Dr. Evan Hersh (w/encl.)
David L. Parker, Esq. (w/o encl.)
Steven L. Highlander, Esq. (w/o encl.)



PATENT
UTSC:648US

APPLICATION FOR UNITED STATES LETTERS PATENT

for

LIPOSOMAL IMEXON

by

Gabriel Lopez-Berestein,

William A. Remers

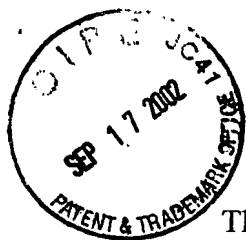
and

Evan Hersh

EXPRESS MAIL MAILING LABEL

NUMBER EL839265561US

DATE OF DEPOSIT November 20, 2001



BACKGROUND OF THE INVENTION

The present application claims priority to U.S. Serial No.09/721,040 filed on November 21, 2000, which was converted by petition to a provisional application. The entire text of the above-referenced application is specifically incorporated herein by reference without disclaimer.

1. Field of the Invention

The present invention relates generally to the fields of pharmaceutical compositions and delivery. More particularly, it concerns formulation and delivery of imexon and/or hydrophobic derivatives thereof in combination with a lipid. The present invention also concerns methods of treating diseases such as cancer with imexon and/or a derivative in combination with a lipid.

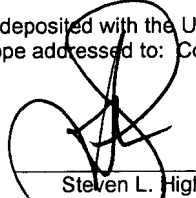
2. Description of Related Art

Diseases such as cancer are a major cause of death of individuals worldwide. Hundreds of aziridines have been synthesized and screened as potential antineoplastic agents (Dermer and Ham, 1969; Goodridge *et al.*, 1963). Most of these compounds are substituted on the aziridine nitrogen with groups such as alkyl, aralkyl, aryl, heterocyclic, acyl, alkanolic, carbamate, and dithiocarbamic acid (Dermer and Ham, 1969). Clinically significant agents have two or more aziridine rings linked through nitrogen to a phosphorus (thio-TEPA) or a quinone ring (diazquone) (Reynolds, 1995; Dorr and Von Hoff, 1994). The aziridine ring also occurs in complex natural products, such as mitomycin C, in which the aziridine nitrogen is unsubstituted (Remers and Iyengar, 1995). Generally, aziridine antitumor agents act by alkylating nucleophilic atoms on guanine residues in DNA (Reynolds, 1995).

In 1975, Bicker reported a type of carcinostatic aziridine, 2-cyanoaziridine-1-carboxamide (Formula 1) (Bicker, 1984; Bicker, 1975). This compound was active against PIE 2-3 sarcoma in Wistar rats, and it had low toxicity. Especially interesting was the observation that it increased the number of leukocytes, rather than decreasing them (Bicker, 1984). In contrast to known aziridines, it showed no alkylating activity toward 4-(4-nitrobenzyl)pyridine (Bicker, 1975). The N-phenyl

Receipt



CERTIFICATE OF MAILING 37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on the date below:	
September 11, 2002 Date	 Steven L. Highlander

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Gabriel Lopez-Berestein, *et al.*

Serial No.: 09/989,695

Filed: November 20, 2001

For: LIPOSOMAL IMEXON

Group Art Unit: 1614

Examiner: Unknown

Atty. Dkt. No.: UTSC:648US

RECEIVED

DEC 12 2002

SECOND REQUEST FOR CORRECTED FILING RECEIPT

TECH CENTER 1600/2900

Commissioner for Patents
Washington, D.C. 20231

Sir:

A corrected filing receipt is hereby requested in view of the error which appears in the original. The U.S. provisional application to which the present case claims priority was incorrectly omitted from the filing receipt. U.S. Application Serial Number 09/721,040 was originally filed as a regular U.S. application on November 21, 2000. On March 30, 2001, Applicants filed with the U.S. Patent Office a Petition to Convert Nonprovisional Application to Provisional Application. U.S. Application Serial Number 09/721,040 was not awarded a provisional serial number, nor did applicants receive response to this petition (copy attached as Exhibit A). The present application, U.S. Application Serial Number 09/989,695, was filed November 20, 2001, claiming priority to Serial Number 09/721,040 (a copy of the priority information in the Specification attached as Exhibit B). The Inventors' Declaration filed March 7, 2002 (attached as Exhibit C) claimed priority

under 35 U.S.C. § 119 to the earlier application, as it was assumed it had been converted to a provisional application.

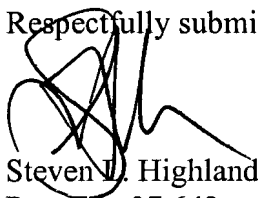
Also attached for the convenience of the Patent and Trademark Office is a photocopy of the original receipt on which this error has been noted in red and a copy of the Response to Request for Corrected Filing Receipt mailed August 29, 2002.

Applicants will inquire with the U.S. Patent Office as to the status of the conversion of U.S. Application Serial Number 09/721,040 to a provisional application. At the time the application is awarded a provisional serial number, applicants will provide this information for the convenience of the Patent Office. Until a provisional serial number is received, please add the following Domestic Priority Data information: --**Claims the benefit of priority from U.S. Application No. 09/721,040 filed November 21, 2000--**.

No fee is believed to be due in connection with the filing of this document. However, should any fee under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to this document, the Commissioner is hereby authorized to deduct said fee from Fulbright & Jaworski Deposit Account No.: 50-1212/UTSC:648US.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,



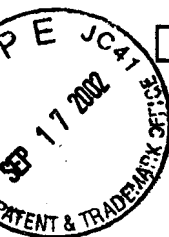
Steven J. Highlander
Reg. No. 37,642
Attorney for Applicant

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 474-5201

Date: September 11, 2002



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COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, DC 20231
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
09/989,695	11/20/2001	Gabriel Lopez-Berestein	UTSC:648US

CONFIRMATION NO. 9730



OC00000008700415

FULBRIGHT & JAWORSKI L.L.P.
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SUITE 2400
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Date Mailed: 08/29/2002

RESPONSE TO REQUEST FOR CORRECTED FILING RECEIPT

Domestic Continuity and Foreign Priority

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In response to your request for a corrected Filing Receipt, the Office is unable to comply with the request because: **DEC 12 2002**

TECH CENTER 1600/2900

- ☐ The priority or continuity claim has not been entered because it was not filed during the required time period. Applicant may wish to consider filing a petition to accept an unintentionally delayed claim for priority. See 37 CFR 1.55 or 1.78.

- ☒ Continuity claimed under 35 USC 120 cannot be added to the Filing Receipt without the applicant supplying the relationship (continuation, divisional, or continuation-in-part) in an Application Data Sheet or amendment to the first page of the specification.

SERIAL NUMBER 09/721,040 11/21/2000

- ☐ A claim for priority cannot be made based on an application filed after the application making the claim.

- ☐ Domestic and foreign priority claims will not be captured in a provisional application. A provisional application is not entitled to a right of priority or to the benefit of an earlier filing date of any other application. See 35 USC 111(b)(7) and 37 CFR 1.53(c)(4).

- ☐ A domestic continuity claim cannot be made to a foreign application and the filing receipt will only list the foreign country, application number, and filing date.

- ☐ Foreign priority will appear on the Filing Receipt in the following order:
Country, Application number, Filing date.

RECEIVED
Date(s) Docketed: <u>Response to</u>
<u>Request for corrected</u>
<u>Filing Receipt rec'd</u>
SEP 06 2002
Client: <u>UTSC:648US</u>
Attorney(s): <u>DLA/SLH</u>
Initials: <u>SSZ</u>

Nina Haropoulos

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APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
✓ 09/989,695	✓ 11/20/2001	1614	585	UTSC:648US	7	32	4

CONFIRMATION NO. 9730

/UPDATED FILING RECEIPT



OC000000007860472

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DEC 12 2002

TECH CENTER 1600/2900

Date Mailed: 04/12/2002

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

 Gabriel Lopez-Berestein, Bellaire, TX;
 William A. Remers, Tucson, AZ;
 Evan Hersh, Tucson, AZ;

Domestic Priority data as claimed by applicant

THIS APPLN CLAIMS BENEFIT OF 09/721,040 11/21/2000

Foreign Applications

If Required, Foreign Filing License Granted 04/12/2002

Projected Publication Date: 05/22/2003

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title

Liposomal imexon

Preliminary Class

RECEIVED	
Date(s) Docketed:	2/20/2002
IDS due	
JUE APR 27 2002	
Client:	UTSC:648US
Attorney(s):	DLP/SLH
Initials:	SD

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Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15**

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